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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ALEXSO, INC., a California corporation,

Plaintiff,

v.

FIRST DATABANK, INC., a Missouri corporation,

Defendant.

Case No.

COMPLAINT FOR:

1. **VIOLATION OF §43(a) OF THE LANHAM ACT;**
2. **CALIFORNIA UNFAIR COMPETITION ACT;**
3. **INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE;**
4. **NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE;**
5. **PRIMA FACIE TORT**

Alexso Inc. ("ALEXSO"), by and through its attorneys, Quarles & Brady LLP, for its Complaint against First Databank, Inc. ("FDB"), states as follows:

Introduction

1. ALEXSO is a small manufacturer of kits for use by pharmacies in compounding topical cream prescription drug products. FDB, a subsidiary of the

Hearst Corporation, is the dominant American publisher of databases that provide information about drug products to the healthcare industry for purposes of decision-making, pricing, and negotiating reimbursement rates. Indeed, FDB holds itself out to the public as "the recognized leader for highly reliable medication decision support" and describes its databases as "integrated within information systems throughout every sector of healthcare including hospitals, long-term care, home health, physician practices, payers, retail pharmacies, mobile health, consumer and professional websites, government organizations, and more." FDB's dominance in this field means that if a company's drug products are not listed in FDB's databases, the company is placed at a fatal competitive disadvantage, because consumers of pharmaceuticals can and do inevitably interpret exclusion from FDB's databases as an affirmative representation by FDB that the excluded products are not approved for sale under federal regulations.

2. This case involves FDB's irrational and legally groundless refusal to list ALEXSO's new kits in its database, a refusal which violates § 43(a) of the Lanham Act, violates California's Unfair Competition Act ("UCA"), and improperly interferes with ALEXSO's prospective economic advantage. ALEXSO seeks injunctive relief under both the Lanham Act and the UCA requiring FDB to list ALEXSO's products in its databases, as well as compensatory and exemplary damages under the Lanham Act and in tort for its lost sales.

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Parties

3. Plaintiff, ALEXSO, is a California corporation, with its principal place of business at 2317 Cotner Ave, Los Angeles, Ca 90077.

4. FDB is a Missouri corporation, with its principal place of business and corporate headquarters at 701 Gateway Blvd., Suite 600, South San Francisco, CA 94080.

Jurisdiction and Venue

5. This Court has subject matter jurisdiction over this matter under 28 U.S.C. § 1331 because the Complaint alleges violations of the federal Lanham Act, and supplemental jurisdiction over the state law claims alleged herein under 28 U.S.C. § 1367 because the claims are so related to the Lanham Act violation as to form part of the same case or controversy.

6. Venue in this Court is proper under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims alleged herein occurred in this District.

General Allegations

7. FDB, a subsidiary of the giant multinational Hearst Corporation, is, according to its own news releases, "the leading provider of drug knowledge that helps healthcare professionals make precise medication-related decisions." FDB describes itself as "the company that virtually launched the medication decision support category."

8. In brochures available on its webpage, FDB further describes its database products as "rigorously compiled using best practices research procedures with extremely thorough validation processes"; as "comprehensively assembled"; and as "continuously and reliable updated, thanks to our strong relationships with manufacturer and wholesaler communities, as well as with federal and state government entities."

9. Indeed, FDB's advertising consistently and purposefully describes its database products in terms that explicitly and implicitly represent them to be comprehensive and reliable sources of information regarding approved drug products, stating, for instance, that FDB's databases have "an unmatched range of tested and proven drug knowledge solutions"; that FDB's databases offer "more comprehensive, configurable, actionable, and intuitive drug knowledge solutions, which meet and exceed customer needs and continually set new standards"; that FDB's databases provide "comprehensive drug knowledge that promotes far more successful administration, analysis, and adjudication"; and that FDB's databases offer "timely and accurate marketplace information," including "drug pricing information."

10. Moreover, again according to its own news releases, as a subsidiary of the Hearst Corporation and as part of the Hearst Health Network, FDB reaches up to 76% of discharged patients in the United States and 133 million insured individuals; and its information may be involved in as many as 1.88 billion retail

pharmacy prescriptions and 3.26 billion prescription claims annually.

11. FDB thus has substantial market power within the healthcare industry, bordering on a monopoly, with regard to providing necessary product and pricing information to hospitals, physician practices, healthcare providers, payers, retail pharmacies, state health programs and others for the purpose of deciding whose drug products to use from among many competitors. If a product is not listed in FDB's databases, the unmistakeable implication is that it either isn't approved for sale by federal regulators, or else simply doesn't exist.

12. ALEXSO for more than six months has been seeking to have eight of its products listed in FDB's databases. The products at issue are all kits for use in compounding topical creams for prescription drug applications, including: (1) Progesterone 10% Kit 60 grams; (2) Biest/Progesterone Kit 60 grams; (3) F.B.L. Transdermal Kit 30 grams; (4) F.B.L. Transdermal Kit 120 grams; (5) K.B.G.L Transdermal Kit 30 grams; (6) K.B.G.L Transdermal Kit 120 grams; (7) A.A.G.C. Transdermal Kit 30 grams; and (8) A.A.G.C. Transdermal Kit 120 grams. Collectively, these products will be referred to herein as the "Kits."

13. ALEXSO provided FDB its initial submission for publication for the Kits on June 24, 2014.

14. Since June 2014, ALEXSO has complied with each request from FDB for additional information about the Kits:

a. ALEXSO provided FDB the package insert (identified as National

Drug Code ("NDC") 40588-200101) and the Medispan FBL 30 Listing (identified as NDC 50488-2001-1) for the Kits on July 17, 2014;

b. ALEXSO provided FDB the Standard Product Listing ("SPL") Validation Confirmation from the Federal Drug Administration ("FDA") for the Kits on August 4, 2014;

c. ALEXSO provided FDB the product pricing, SPL effective date, package insert, and product label for the Kits on September 25, 2014;

d. Also on September 25, 2014, ALEXSO provided FDB a statement that FDA approval would not be required for the Kits because the FDA had already approved it for marketing in the United States under SPL Marketing Category C96793, "Bulk Ingredient for Human Prescription Compounding";

e. On October 27, 2014, ALEXSO provided NDC numbers for each raw ingredient contained in the Kits to be added to the cream base known as "TeroDerm," including Fluriprofen powder (NDC number 50488-1007-1), Baclofen powder (50488-1005-1), and Lidocaine powder (50488-1011-3). Notably, each of these component parts for the Kits is already listed by FDB.

15. These submissions by ALEXSO demonstrate that the Kits are marketed for compounding uses only; are comprised of components with individual FDA marketing approval; and have received SPL approval from the FDA for the

Kits as a whole, even though such approval is not required. As such, there is no reasonable impediment to the Kits being listed in FDB's databases.

16. In spite of ALEXSO's efforts, FDB has refused to list the Kits. Instead, FDB told ALEXSO via email on November 7, 2014 that it will not "add compounding kits to the database unless we receive notification from the FDA that they can be marketed without approval."

17. FDB has taken this position despite being fully aware of the following facts:

a. The practice of pharmacy compounding remains subject to state law regulation and is only minimally subject to FDA oversight.

b. Congress has established that the provisions of the federal Food, Drugs and Cosmetics Act pertaining to product marketing, adulteration, and labeling "shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order…" 21 U.S.C.A. §353a(a).

c. State-licensed pharmacists and physicians may compound drug products using bulk substances like the ones contained in the Kits. *Id.* at (b)(1).

d. The Kits' component products are all individually approved by the FDA, acquired from an FDA-registered distributor, and the Kits are packaged in ALEXSO's FDA-registered facility.

e. The FDA's policies clearly permit companies to market compounding kits without the kind of approval FDB demands. For instance, the FDA's Data Standards Update ("Update") provides guidance on how drug product manufacturers should develop their labels in compliance with FDA's requirements. The Update includes an approved list of thirty (30) discrete SPL categories, including a category defined as Bulk Ingredients for Human Prescription Compounding (C96793). Article 3.1.6 to the Update pertains to Kits, Parts, Components and Accessories, and it establishes that "Products may be combined in various ways such as … Products sold separately but meant to be used together."

18. In sum, FDB is fully aware that FDA approval for the Kits is unnecessary, because federal law and FDA policy is clear that products manufactured on a per-prescription basis (*i.e.*, drug products compounded by pharmacists for individual patients based on a doctor's prescription) are not subject to the federal drug manufacturing approval and marketing requirements. FDB's refusal to list ALEXSO's Kits is thus legally groundless and arbitrary. Moreover, FDB's refusal to list ALEXSO's Kits in its databases constitutes an affirmative and willfully false representation to consumers that ALEXSO's Kits are not approved for sale by federal regulations, even though FDB is well aware that the Kits are not subject to FDA approval.

19. Indeed, FDB's own prior conduct with respect to competitors' kit products demonstrates that its refusal to list ALEXSO's Kits is baseless and arbitrary. On October 27, 2014 and again on November 10, 2014, ALEXSO also provided FDB with a list of 25 kits that FDB currently lists that are manufactured by companies other than ALEXSO, and that contain component products that are either identical or substantially similar to those contained in ALEXSO's Kits. The list, entitled "Appendix A, Identification of Comparable Kits Published by FDB," is attached hereto as **Exhibit A** and incorporated herein by reference.

20. The disparate treatment by FDB of ALEXSO's Kits puts it at a severe competitive disadvantage in comparison to the 25 competitors' kits FDB already lists, making it essentially impossible for ALEXSO to compete in the marketplace and sell its products. In addition, FDB's exclusion of ALEXSO's Kits, while including other substantially similar Kits, operates as a willful disparagement of the Kits. FDB's arbitrary and legally baseless actions in refusing to list ALEXSO's Kits have caused and threaten to cause ALEXSO to lose significant business opportunities, including lost sales of the Kits.

FIRST CLAIM FOR RELIEF

VIOLATION OF § 43(a) OF THE LANHAM ACT

21. ALEXSO hereby incorporates the allegations asserted in paragraphs 1 through 20, hereinabove as fully set forth at length herein.

22. Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)) provides that

"[a]ny person who, on or in connection with any goods or services… uses in commerce any… false or misleading representation of fact… which is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person… shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act."

23. FDB's conduct described above in irrationally refusing to list ALEXSO's Kits in its databases, without any legal basis or business justification, and where FDB did list other similar or identical products by other manufacturers, constitutes a false and misleading representation of fact, namely, that ALEXSO's Kits are not approved for sale under federal regulations governing drug products, while the other substantially similar products are so approved.

24. FDB's databases, by excluding ALEXSO's Kits, are likely to cause confusion to consumers, who will inevitably conclude that ALEXSO's Kits are not approved for sale by the governing federal regulatory agency.

25. This Court has the power under 28 U.S.C. § 1116(a) to grant injunctions to prevent violations of § 43(a) of the Lanham Act.

26. ALEXSO is entitled to an injunction requiring FDB to include ALEXSO's Kits in FDB's databases for use by the healthcare industry.

27. Further, ALEXSO is entitled under 28 U.S.C. § 1117(a) to recover the damages it has suffered in the form of lost sales due to FDB's refusal to list ALEXSO's Kits in FDB's databases, including actual damages and exemplary damages not exceeding three times those actual damages, as well as the costs of this action and its reasonable attorney fees.

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SECOND CLAIM FOR RELIEF

CALIFORNIA UNFAIR COMPETITION ACT

(Bus. & Prof. Code §17200)

28. ALEXSO hereby incorporates the allegations asserted in paragraphs 1 through 27, hereinabove as fully set forth at length herein.

29. Section 17200 of the Unfair Competition Act in the California Business and Professions Code defines unfair competition to include unfair business acts or practices.

30. FDB's conduct described above in irrationally refusing to list ALEXSO's Kits in its databases, without any legal basis or business justification, and where FDB did list other similar or identical products by other manufacturers, is unfair, because it substantially injures consumers of such kits by restricting their choices in the healthcare marketplace, produces no countervailing benefits to consumers or competition, and because consumers, at the end of a distribution and reimbursement chain involving companies like FDB, ALEXSO, healthcare providers, hospitals, and third-party payers like insurance companies, could not have reasonably avoided the injury, since consumers would have no way of knowing that ALEXSO's Kits were not among the pharmacy compounding kits included in FDB's databases.

31. This Court has the power under § 17203 of the UCA to enjoin any person who engages, has engaged, or proposes to engage in unfair competition or unfair business practices.

32. ALEXSO is entitled under the UCA to a preliminary and permanent injunctive relief requiring FDB to include ALEXSO's Kits in FDB's databases for use by the healthcare industry.

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THIRD CLAIM FOR RELIEF

INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

33. ALEXSO hereby incorporates the allegations asserted in paragraphs 1 through 32, hereinabove as fully set forth at length herein..

34. FDB's conduct as described above in irrationally refusing to list ALEXSO's Kits in its databases improperly and unlawfully blocked ALEXSO from participating in the marketplace for such pharmacy compounding kits.

35. ALEXSO had an economic relationship with customers for its Kits, with the reasonable probability of future economic benefits to ALEXSO from sales of the kits.

36. FDB understood, by virtue of its market dominance in the field of providing information to health care providers for the use in decision-making regarding drug products, including products such as the ALEXSO Kits, that refusing to list ALEXSO's Kits in its databases would cause ALEXSO harm to its economic relationships with its customers.

37. FDB intentionally excluded ALEXSO's Kits from the FDB databases without any legal basis or business justification. FDB's intentional exclusion of ALEXSO's Kits from the FDB databases ignored and contradicted statutory and regulatory direction regarding the treatment of pharmacy compounding kits under federal law.

38. FDB's exclusion of ALEXSO's Kits from its databases has disrupted existing and potential economic relationships between ALEXSO and its customers, thereby injuring ALEXSO in the form of lost sales opportunities.

39. ALEXSO is entitled to damages based on FDB's intentional interference with ALEXSO's prospective economic advantage in an amount sufficient to compensate ALEXSO for profits on sales it has lost due to FDB's refusal to list the Kits.

FOURTH CLAIM FOR RELIEF

NEGLIGENT INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE

40. ALEXSO hereby incorporates the allegations asserted in paragraphs 1 through 39, hereinabove as fully set forth at length herein.

41. FDB's conduct as described above in irrationally refusing to list ALEXSO's Kits in its databases improperly and unlawfully blocked ALEXSO from participating in the marketplace for such pharmacy compounding kits.

42. ALEXSO had an economic relationship with customers for its Kits, with the reasonable probability of future economic benefits to ALEXSO from sales of the kits.

43. FDB understood, by virtue of its market dominance in the field of providing information to health care providers for the use in decision-making regarding drug products, including products such as the ALEXSO Kits, that

refusing to list ALEXSO's Kits in its databases would cause ALEXSO harm to its economic relationships with its customers.

44. FDB negligently excluded ALEXSO's Kits from the FDB databases without any legal basis or business justification, and without due care in investigating the statutory and regulatory framework governing the marketing of such pharmacy compounding kits. FDB's negligent exclusion of ALEXSO's Kits from the FDB databases ignored and contradicted statutory and regulatory direction regarding the treatment of pharmacy compounding kits under federal law.

45. FDB's exclusion of ALEXSO's Kits from its databases has disrupted existing and potential economic relationships between ALEXSO and its customers, thereby injuring ALEXSO in the form of lost sales opportunities.

46. ALEXSO is entitled to damages based on FDB's intentional interference with ALEXSO's prospective economic advantage in an amount sufficient to compensate ALEXSO for profits on sales it has lost due to FDB's refusal to list the ALEXSO kits.

FIFTH CLAIM FOR RELIEF

PRIMA FACIE TORT

47. ALEXSO hereby incorporates the allegations asserted in paragraphs 1 through 46, hereinabove as fully set forth at length herein.

48. FDB's conduct as described above in irrationally refusing to list ALEXSO's Kits in its databases is without legal or business justification.

49. FDB understood that, by virtue of its market dominance in the field of providing information to health care providers for the use in decision-making regarding drug products, including products such as the ALEXSO Kits, that refusing to list ALEXSO's Kits in its databases would cause ALEXSO harm to its business interests.

50. FDB nevertheless has intentionally refused to list ALEXSO's Kits in its databases, thereby causing ALEXSO harm.

51. FDB's conduct was culpable and not justifiable under the circumstances described above, particularly since FDB treated ALEXSO's Kits differently than it treated similar products from other manufacturers.

52. ALEXSO is entitled to damages based on FDB's tortious conduct in an amount sufficient to compensate ALEXSO for profits on sales it has lost due to FDB's refusal to list the ALEXSO kits.

WHEREFORE, Plaintiff Alexso, Inc. prays for judgment against Defendant First Databank, Inc. on all Claims for Relief, as follows:

1. For an injunction compelling FDB to include ALEXSO's kit products, described herein, within FDB's databases;

2. For compensatory damages in an amount to be determined at trial, reflecting lost sales suffered by ALEXSO caused by FDB's conduct, plus interest;

3. For exemplary damages not exceeding three times its compensatory damages;

4. For an award of ALEXSO's reasonable attorney fees and costs as may be permitted by law; and

5. For all additional relief the Court deems just and proper.

LEBEDEV, MICHAEL & HELMI

March 12, 2015

By: /s/ Gennady L. Lebedev
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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this action pursuant to F.R.C.P. 38 and the Seventh Amendment of the Constitution on all issues herein that may by tried by jury.

DATED: March 12, 2015

LEBEDEV, MICHAEL & HELMI

By: /s/ Gennady L. Lebedev
Gennady L. Lebedev, Esq., Attorneys for Plaintiff, ALEXSO, INC.

Exhibit A

Identification of Comparable Kits Published by FDB

1. Topical Kit EnovaRX Ibuprofen 10% 60 gm (NDC: 76420-0980-06)
2. Topical Kit EnovaRX Ibuprofen 10% 120 gm (NDC: 76420-0981-01)
3. Topical Kit EnovaRX Cyclobenzaprine 2% 60 gm (NDC: 76420-0991-06)
4. Topical Kit EnovaRX Cyclobenzaprine 2% 120 gm (NDC: 76420-0992-01)
5. Topical Kit EnovaRX Amitriptyline 2% 60 gm (NDC: 76420-0710-06)
6. Topical Kit EnovaRX Amitriptyline 2% 120 gm (NDC: 76420-0710-01)
7. Topical Kit EnovaRX Tramadol 5% 60 MG (NDC: 76420-0950-06)(CIV)
8. Topical Kit EnovaRX Tramadol 5% 120 gm (NDC: 76420-0951-01)(CIV)
9. Topical Kit EnovaRX Lidocaine 5% 60 gm (NDC: 76420-0960-06)
10. Topical Kit EnovaRX Lidocaine 5% 120 gm (NDC: 76420-0961-01)
11. Topical Kit EnovaRX Lidocaine 10% 60 gm (NDC: 76420-0970-06)
12. Topical Kit EnovaRX Lidocaine 10% 120 gm (NDC: 76420-0971-01)
13. Topical Kit EnovaRX Naproxen 10% 60 gm (NDC: 76420-0940-06)
14. Topical Kit EnovaRX Naproxen 10% 120 gm (NDC: 76420-0941-01)
15. Topical Kit EnovaRX Baclofen External Cream 1% 60 gm (NDC: 76420-0930-06)
16. Topical Kit EnovaRX Baclofen External Cream 1% 120 gm (NDC: 76420-0931-01)
17. Topical Kit First-Omeprazole Oral Suspension 2 MG/ML90ML (NDC: 65628-0070-03)
18. Topical Kit First-Lansoprazole Oral Suspension 3 MG/ML (NDC: 65628-0080-03)
19. Topical Kit First-Hydrocortisone External Gel 10% 60 gm (NDC: 65628-0010-01)
20. Topical Kit First-Testosterone Transdermal Ointment 2% 60 gm (NDC: 65628-0020-01)
21. Topical Kit First-Testosterone MC Transdermal Cream 2% 60 gm (NDC: 65628-0021-01)
22. Topical Kit First-Mouthwash BLM Mouth/Throat Suspension 237 ML (NDC: 65628-0050-01)
23. Topical Kit First-Dukes Mouthwash Mouth/Throat Suspension 237 ML (NDC: 65628-0052-01)
24. Topical Kit First-Progesterone VGS 25 Vaginal Suppository 25 MG 30 EA (NDC: 65628-0060-01)
25. Topical Kit First-Progesterone VGS 50 Vaginal Suppository 50 MG 30 EA (NDC: 65628-0061-01)